REMARKS

Reconsideration of the application is requested in view of the foregoing amendments and the following remarks addressed to the Examiner during an interview on October 29, 1984, which is acknowledged with thanks.

Claims in the case are 18-42. In the interview, amendments to the claims were discussed to obviate rejections under 35 USC 101, 103 and 112 as set forth in the Office Action of August 10, 1984. The claims have been amended accordingly. Claims 18-32 and 34 correspond to original claims 1-16; new claim 33 is a dependent claim to the gallium compounds disclosed at page 7 of the specification. New claims 35-39 are the same as claim 34 but depend from claims 19-23. New claims 40 and 41 parallel claim 18 and are directed to reducing bone pain and fractures as disclosed at pages 2 and 22 of the specification. New claim 42 parallels claim 23 and is directed to the intra-oral formulation.

A fee authorization for the new claims is enclosed.

1. Toxicity of gallium compounds

The safety of gallium compounds has been a subject of clinical testing for nine years. The enclosed publication of co-inventor Raymond Warrell, Jr., (Cancer Treatment Reports 67 (1983)) discloses studies of cancer patients

treated with doses of gallium even greater than disclosed in the present application. Results show lack of nephrotoxicity under this regimen. The second publication by inventors Warrell and Bockman, (J. Clin. Invest. 73 1487 (1984), at page 1488 shows that treatment of cancer patients with gallium ion was well tolerated. The specification (page 15), discloses that no toxic reactions were observed in a dog and that gallium is not cytotoxic to cultured cells (page 7) at therapeutic dose levels.

2. Therapeutic agent in gallium

The present invention discloses the use of gallium compounds and that the effective agent is the gallium in these compounds. Any biocompatible, pharmaceutically acceptable gallium compounds may be used; the choice of delivery compound may be determined by factors such as commercial accessibility, solubility characteristics and mode of administration.

3. Preventive and therapeutic use of gallium compounds

During the interview it was agreed to amend claim 1 (now claim 18) to direct it to a method effective against excessive calcium loss. It should be understood that this phrase does not exclude the use of gallium compounds for preventing or treating calcium loss. Gallium compounds are of use as claimed in preventing recurrence of cancer

produced hypercolania and also of use in groups at high risk for osteoporosis and periodontal disease.

4. Dissociation of use of Gallium as anti-cancer agent from use as anti-tumor agent.

Bone disorders are associated with cancer and can be effectively treated and prevented by appropriate gallium therapy. As the specification discloses on page 22 to 23, gallium has been shown to be effective in treating bone disorders but no disclosure is made that this constitutes a type of primary anti-cancer treatment. Thus the separation of the therapeutic effectiveness on excess loss of calcium from bone can be dissociated from any primary cytotoxic effect on tumors.

In view of the above, reconsideration of the application and amendments and allowance of the application are respectfully requested.

Very truly yours,

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